

REMARKS

In an office action dated April 27, 2004, the Examiner rejected Claims 1-10 of the present invention.

In the office action, the Examiner rejects Claims 1-10 under 35 U.S.C. §103, as being unpatentable over Kittrell et al (U.S. 5,304,173) in view of Wong et al (U.S. 5,038, 039). Applicant respectfully disagrees with Examiner's contentions.

For a §103 obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1996).

Claim 1 of the present invention recites a "system for analysis of an in vivo biological sample, comprising: a middle infrared radiation source configured to provide radiation in a spectral range of about 2.5 microns to about 20 microns; an optical fiber coupled to said middle infrared radiation source, said optical fiber being substantially transparent in said spectral range of about 2.5 microns to about 20 microns; an interchangeable fiberoptic probe associated with said optical fiber and configured to direct radiation from said radiation source to said in vivo biological sample; ... and a Fourier transform infrared spectrophotometer operatively coupled to said detector and configured to detect radiation in said spectral range ...."

Kittrell teaches analysis of an *in vitro* sample, wherein spectral diagnostic studies are made on samples “obtained and examined within 24 hours of extraction” and samples are “placed in quartz cuvettes, immersed in saline solution. (Col. 21, lines 49-64). A sample that is extracted and placed in a cuvette is clearly an *in vitro* sample. Furthermore, although Kittrell teaches a fiberoptic light guide, it fails to teach a Fourier transform infrared spectrophotometer. Therefore, Kittrell fails to teach the use of an *in vivo* sample and a Fourier transform infrared spectrophotometer as recited in Claim 1 of the present invention.

Wong only teaches analysis of an *in vitro* sample, not an *in vivo* sample. When samples are “cut”, “frozen”, “stored until used”, and “placed in the sample cell of the sample cell and holder” as in Wong (Col. 3, lines 37-41; Col. 4, lines 52-67), they cannot be deemed to be *in vivo*. There is no suggestion in Wong that *in vivo* samples should be used. By teaching only the use of *in vitro* samples, which are completely different from *in vivo*, Wong teaches away from the present invention. Furthermore, although Wong discloses the use of a Fourier transform infrared spectrophotometer, it does not teach the use of an optical fiber or a fiberoptic probe. Therefore, Wong fails to teach the use of an *in vivo* sample and an optical fiber as recited in Claim 1 of the present invention.

Since neither Kittrell nor Wong teaches the analysis of an *in vivo* sample, their combination does not teach the analysis of an *in vivo* sample, as claimed in the present invention. Therefore, the rejection should be removed.

Even if Kittrell is deemed to teach the analysis of an *in vivo* sample, it would not be sufficient to support a finding of obviousness. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.02. Therefore, if Wong (*in vitro*) was

combined with Kittrell (in vivo - in this scenario), the proposed modification (in vivo) would change the principle of operation of Kittrell.

Furthermore, there is no motivation to combine Kittrell and Wong in order to arrive at a system for analysis of an *in vivo* biological sample that comprises an optical fiber, a fiberoptic probe and a Fourier transform infrared spectrophotometer as claimed in the present invention. Neither Kittrell nor Wong suggest any motivation to arrive at such a combination. Therefore, the rejection should be removed.

As mentioned above, Claim 1 of the present invention recites a system for analysis of an in vivo biological sample, comprising a “radiation source configured to provide radiation in a spectral range of about 2.5 microns to about 20 microns; an optical fiber ... being substantially transparent in the spectral range of about 2.5 microns to about 20 microns; ... and a Fourier transform infrared spectrophotometer ... configured to detect radiation in said spectral range of about 2.5 microns to about 20 microns.”

Kittrell does not teach the specific spectral range of about 2.5 microns to about 20 microns. Examiner contends that it would have been obvious to someone of ordinary skill in the art at the time of the invention that spectral analysis could be performed with a standard Fourier spectrophotometer operating in the claimed spectral range. (*Office Action*, 8/14/02, page 3). However, as previously pointed out in both of Applicant's responses to the Office Action dated April 25, 2003, reliance on the obviousness rejection based upon obvious ranges is not sufficient without evidence from the prior art. It is respectfully requested that evidence be provided, if possibly citable from the prior art references, to prove that the prior art teaches the claimed spectral ranges, or the rejection must be withdrawn. Broad conclusory statements standing alone are not evidence. MPEP 2144.03(C). Therefore, Kittrell does not teach the claimed range limitation of the present invention.

Despite Examiner's assertion that Wong discloses a device operating in the mid-infrared range as set forth in the claims (*Office Action*, 4/27/04, page 2), Wong is directed towards use of an *in vitro* sample, not an *in vivo* sample as claimed in the present invention. Therefore, even if Wong teaches the claimed range limitation of the present invention, there is no motivation to combine Wong with Kittrell in order to arrive at the claimed range since Wong is directed towards a completely different principle of operation (*in vitro*) than the present invention (*in vivo*).

Neither Kittrell nor Wong suggest any motivation to combine in order to arrive at a system for analysis of an *in vivo* sample using a spectral range of about 2.5 microns to about 20 microns. Therefore, the rejection should be removed.

Claims 2-5 stand rejected under 35 U.S.C. §103, as being unpatentable over Kittrell et al (U.S. 5,304,173) in view of Wong et al (U.S. 5,038, 039). Applicant respectfully disagrees with Examiner's contentions.

If an independent claim is non-obvious under 35 U.S.C §103, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). Claim 1 is non-obvious over the prior art, therefore, dependent Claims 2-5 are also non-obvious over the prior art.

Reconsideration and withdrawal of these rejections is respectfully requested.

Claim 6 stands rejected under 35 U.S.C. §103, as being unpatentable over Kittrell in view of Wong. Applicant respectfully disagrees with Examiner's contentions.

Claim 6 of the present invention recites "a method for non-invasive analysis of an *in vivo* biological sample, comprising: obtaining a first Fourier transform infrared spectrum of a normal *in vivo* biological sample using a fiberoptic probe operating in an attenuated total reflection mode; obtaining a second Fourier transform infrared spectrum of an abnormal *in vivo* biological sample using said fiberoptic probe operating in said

attenuated total reflection mode; and comparing at least one selected absorption band in said first Fourier transform infrared spectrum to at least one selected absorption band in said second Fourier transform infrared spectrum.”

The same arguments made above for Claim 1 with respect to the present inventions use of *in vivo* samples, a fiberoptic probe and a Fourier transform, are applicable to Claim 6 as well.

Additionally, attention should be directed to the attenuated total reflection limitation of Claim 6.

Kittrell does not teach the attenuated total reflection limitation as recited in Claim 6 of the present invention. Examiner even states that “Kittrell does not teach spectral analysis with a probe using attenuated total reflectance (ATR).” (*Office Action*, 4/25/03, page 3).

Although Wong briefly mentions the use of attenuated reflectance characteristics, Wong does not teach the use of ATR with a fiberoptic probe, as recited in Claim 6 of the present invention.

Since neither Kittrell nor Wong teaches the use of a fiberoptic probe in ATR mode, their combination does not teach the use of a fiberoptic probe in ATR mode, as claimed in the present invention. Therefore, the rejection should be removed.

Even if Wong did teach the use of a fiberoptic probe in ATR mode, it would not be sufficient to support a finding of obviousness. As previously stated, Wong is directed towards the use of an *in vitro* sample, not an *in vivo* sample as claimed in the present invention. Therefore there is no motivation to combine Wong with Kittrell in order to arrive at the claimed use of a fiberoptic probe in ATR mode since Wong is directed towards a completely different principle of operation (*in vitro*) than the present invention (*in vivo*). Furthermore, neither Kittrell nor Wong suggest any motivation to

combine in order to arrive at the use of a fiberoptic probe in ATR mode. Therefore, the rejection should be removed.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 7-10 stand rejected under 35 U.S.C. §103, as being unpatentable over Kittrell et al (U.S. 5,304,173) in view of Wong et al (U.S. 5,038, 039). Applicant respectfully disagrees with Examiner's contentions.

If an independent claim is non-obvious under 35 U.S.C §103, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). Claim 6 is non-obvious over the prior art, therefore, dependent Claims 7-10 are also non-obvious over the prior art.

Reconsideration and withdrawal of these rejections is respectfully requested.

Applicant requests that this application be allowed. If the Examiner has any questions regarding this application, the Examiner may telephone the undersigned attorney at 775-586-9500.

Respectfully submitted,  
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